



Retention Evaluation of Fissure Sealants Applied Using Self-Etch and Conventional Acid-Etch Techniques: A Randomized Control Trial Among Schoolchildren

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Abstract: Purpose: The purpose of this study was to evaluate the clinical retention capabilities of a self-etch adhesive system (experimental group) and conventional acid-etch (control group) techniques and compare the caries incidence within six months and 24 months of follow-up periods. **Methods:** A total of 47 healthy children with a mean age of 9.7 years and either sound or noncavitated erupted permanent first molars were included in the trial. A total of 188 molars were randomly assigned in a split-mouth design for the self-etch mode in the universal adhesive or conventional acid-etch. Differences in sealant retention and caries incidence were compared at six and 24 months after sealant placement using a chi-square test. **Results:** Within 24 months of follow-up, the retention of fissure sealant applied using conventional acid etching (41 out of 66; 62.1 percent) was significantly higher ($P < 0.05$) than that of the fissure sealant applied using self-etching mode in the universal adhesive system (17 out of 66; 25.8 percent). There was no significant difference in caries incidence between the two groups up to 24 months after sealant placement. **Conclusion:** With 24 months of follow-up, the retention of the conventional acid-etching technique were superior to those of the self-etch technique. (*Pediatr Dent* 2022;44(4):249-54) Received March 6, 2022 | Last Revision June 6, 2022 | Accepted June 13, 2022

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The application of sealants to newly erupted posterior teeth is considered the best approach for preventing lesions caused by pit and fissure caries.¹ Moreover, fissure sealant application produces a physical barrier preventing the access of bacteria and nutrients into the occlusal pits and fissures, thereby inhibiting the formation of caries.²

The application of phosphoric acid increase porosity of to enamel surfaces to increase surface area before fissure sealant placement has been considered the gold standard approach for many years.³ In addition, using an adhesive system before fissure sealant placement can enhance retention capability.⁴⁻⁶ A self-etch adhesive system reduces the time required for the fissure sealant application and, thus, is less technique-sensitive than an etch-and-rinse adhesive system. This more efficient technique can aid avoidance of moisture contamination by shortening the time of clinical application, especially when saliva isolation is difficult.^{7,8} The origins of self-etch adhesive systems can be traced back to the sixth and seventh generations of bonding agents in the late 1990s and early 2000s.⁹

In 2011, a one-bottle universal adhesive multimode was developed to represent the latest bonding generation in the

market, rendering dental procedures user-friendly. The one-bottle universal adhesive multimode enables clinicians to use the material as a self-etch or an etch-and-rinse adhesive for the preparation of enamel surfaces before the application of fissure sealants. Botton et al.¹⁰ recommended well-designed randomized control trials with large sample sizes to assess the clinical effectiveness of resin-based fissure sealants applied under different protocols using universal adhesives for the evaluation of retention and incidence of caries.¹⁰

Therefore, the purpose of this study was to evaluate and compare the clinical retention capabilities of a self-etch agent and conventional acid-etch techniques in the preparation of enamels before sealant placement. Additionally, this study aimed to compare the incidence of caries following the sealant dislodgement of a self-etch agent and conventional acid-etch techniques.

Methods

Study design and ethical approval. This study was designed to be a split-mouth, single-blinded, and randomized control clinical trial conducted at the Faculty of Dentistry, University of Malaya, Kuala Lumpur, Malaysia. The study was approved by the Malaysian Ministry of Education, and consent forms were obtained from the participants' parents or guardians. The trial protocols were recorded under the Australia New Zealand Clinical Trials Registry (ANZCTR; registration number ACTRN1261900-1250123). The trial protocol followed the recommendations of the Consort Statement and was approved by the Medical Ethics Committee, Faculty of Dentistry, University of Malaya, Kuala Lumpur, Malaysia (no. DF D1814/0052/2024P).

Subject allocation and recruitment. Schoolchildren aged between eight and 10 years and with fully erupted permanent first molars were included in the study. All permanent first molars identified for sealant placement were sound according to the International Caries Detection and Assessment System (ICDAS) 0 or noncavitated ICDAS 0A (ICDAS 01, 02). In

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this study, the caries incidence in the pits and fissures of the permanent first molars was assessed based on the ICDAS scores (i.e., ICDAS 0 equals sound tooth, ICDAS 1 and 2 were combined to represent 0A equals noncavitated caries lesion, ICDAS 3 equals cavitated caries lesion in enamel, and ICDAS 5 equals cavitated caries lesion in dentin).¹¹ Uncooperative children, mentally challenged or physically disabled children, and children diagnosed with ICDAS 03 or with previously restored teeth or sealed permanent first molars were excluded from the study. Examiner training and calibration exercises were conducted before the trial. Reliability between the examiner and an experienced pediatric dentist consultant was assessed in a pilot study, which was conducted on 40 molars. The Kappa scores for inter- and intraexaminer reliability were 0.85 and 0.90, respectively, indicating a strong level of agreement between the examiners.¹²

The sample size was calculated based on Botton et al.'s systematic review and meta-analysis using PS calculation software (version 3.1.2, Vanderbilt School of Medicine, Nashville, Tenn., USA)¹⁰ A total of 52 molars were needed per group to meet the parameters, such as an alpha error level of five percent, power of 80 percent, the possibility of the outcome for the control group equaling 0.582, and the possibility of the outcome for the test group equaling 0.286. However, significance was improved by inflating the sample size to 94 molars per group, taking into consideration any potential for attrition.

Participants were recruited from multiple classes within a single primary school in Kuala Lumpur. Eighty-three participants were initially screened, and their eligibility for the clinical trial was determined. Consent forms were obtained from 58 participants who met the study inclusion criteria. Of the 58 consent forms issued, 47 participants agreed to participate in the study. In the current trial, the split-mouth technique allows the inclusion of four teeth (all permanent first molars) per participant; thus, a total of 188 molars for sealing were obtained (94 in each group). The two groups were the conventional acid-etch technique as the control arm and the self-etch group as the experimental arm. The allocation ratio was equally divided between the two arms in the test and control groups.

Randomization. After the recruitment of participants eligible for the trial, randomization was conducted at two levels (Figure). The Random.org website was used as a sequence generator to produce a randomized list of the eligible participants. A pediatric dentist consultant who was not participating in the trial used the lottery approach to assign treatment sequence alternatives based on quadrant level (i.e., two maxillary and two mandibular molars assigned) for all the recruited participants. The results of the allocation were recorded, sealed in envelopes, and released to the operator before enamel preparation. Randomization ensured that each arch (i.e., maxillary and mandibular) included a control and test group (i.e., two control and two test teeth per subject). To achieve the blinding rule, the parents and participants were unaware of the enamel treatment options provided to them.

Sealing protocol. Before fissure sealant placement, the occlusal surfaces of the molars were washed and cleaned thoroughly with a fluoride-free slurry of pumice using a bristle brush for the elimination of accumulated food debris and plaque attached to the teeth. Subsequently, the isolation process was conducted using cotton rolls with adequate suctioning with a four-handed technique to avoid any moisture contamination during the procedure. All applications were performed by a single clinician who had undergone training and calibration exercises.

Using the conventional acid-etch technique, the occlusal surfaces of the molars were treated with 32 percent phosphoric acid etching gel (Scotchbond™ Universal Etchant, St. Paul, Minn., USA) according to the manufacturer's instructions; it was applied with a microbrush on the occlusal surfaces for 20 seconds, rinsed for 30 seconds, and dried using a 3-1 syringe for 15 seconds. However, using the self-etch mode, the single bond universal adhesive (Scotchbond™ Universal Etchant) was

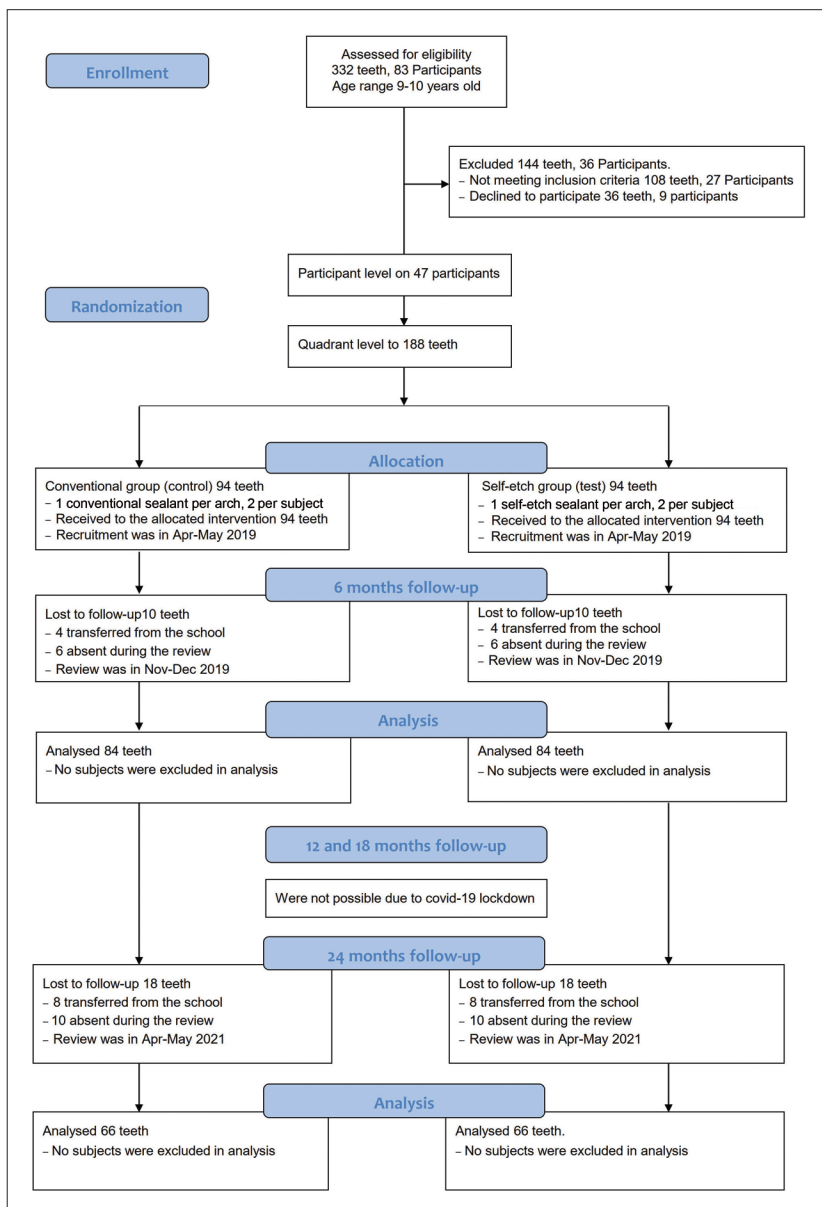


Figure. Flowchart.

applied to the pit and fissures of the molars using a micro-applicator according to the manufacturer's instructions, rubbed for 20 seconds, dried using a 3-1 syringe for five seconds, and finally lightly cured for 10 seconds.

A sealant (3M™ Clinpro™ ESPE, St. Paul) was placed on the occlusal surface and then gently introduced into the pit and fissures with the tip of a periodontal probe to ensure no voids or air entrapment was present during the procedure. Then, it was cured with a light-emitting diode curing light (model no. 921638, Demi™ Plus, Brea, Calif., USA) with an output intensity of 450 mW/cm² and a 450 nm wavelength. The curing tip was placed close to the sealant for 20 seconds. The resin-based sealants were checked for voids with a sharp dental explorer. The occlusion was examined using an articulation paper and adjusted using a finishing bur.

The retention of fissure sealants was evaluated six and 24 months after the intervention as the primary outcome by a single trained and calibrated clinician (pediatric dentist resident) who was blinded to the tooth allocation. The evaluation criteria (i.e., completely retained, partially retained, and completely lost) described by Simonsen were used.¹³ The progress of occlusal caries was assessed with ICDAS based on

fissure sealant placement in the different arms within six and 24 months of follow-up for molars with partial and total sealant dislodgement and was considered the secondary outcome.

Data analysis. Data were collected and analyzed using SPSS 26.0 software for Windows (SPSS®, Chicago, Ill., USA). Demographic variables (i.e., age, sex, and ethnicity) were recorded at baseline and within six and 24 months of follow-up. A chi-square test was performed to compare the two groups (i.e., conventional acid-etch and self-etch) regarding the retention of fissure sealants and caries incidences of the permanent first molars at six and 24 months after sealant placement. The significance level was set at 0.05.

Results

The flow chart of the study population in the Figure shows that a total of 47 schoolchildren with 188 molars were recruited at the beginning of the study. Of these children, 42 were reexamined during six months of follow-up, representing a follow-up rate of 89.4 percent (42 out of 47). The 24 month follow-up was reduced to 78.8 percent (33 out of 42), of children that returned for reexamination (Table 1). In addition, the number of children aged 10 years (32 of 47, 68.1 percent) was higher than children aged nine years (15 of 47, 31.9 percent) at baseline, and the number of male children (24 out of 47, 51.1 percent) was slightly higher than that of female children (23 out of 47, 48.9 percent). Most children were Malay (45 out of 47, 95.7 percent) or Indian (two out of 47, 4.3 percent).

Retention of fissure sealants six and 24 months after sealant application in the control (conventional acid-etch) and test (self-etch) groups were evaluated using Simonsen's criteria (Table 2). The percentage of completely retained sealants was higher in the conventional acid-etch group (71 of 84, 84.5 percent) than in the self-etch group (24 of 84, 28.5 percent) at the six-month follow-up. Meanwhile, the proportion of partially retained sealants was higher in the self-etch group (16 of 84, 19.0 percent) than in the conventional acid-etch group (10 of 84, 12.0 percent). The number of sealants lost in the self-etch group (44 of 84, 52.5 percent) was higher than that in the conventional acid-etch group (7 of 84, 8.3 percent). The difference in fissure sealant retention between the two techniques was statistically significant ($P < 0.001$).

At 24 months follow-up, the percentage of completely retained sealants was higher in the conventional acid-etch group (17 of 66, 25.8 percent) than that in the self-etch group (7 of 66, 10.6 percent). Likewise, the proportions of partially retained sealants were higher than in the conventional acid-etch group (18 of 66, 27.3 percent) compared to the self-etch group (seven out of 66, 10.6 percent). By contrast, more than half of the sealants were completely lost in the self-etch group (42 of 66, 63.6 percent), versus those in the conventional acid-etch group (seven out of 66, 10.6 percent). However, the difference in fissure sealant retention between the two techniques was statistically significant ($P < 0.001$; Table 2).

The incidence of caries on the pits and fissures of the permanent first molars was determined using ICDAS scores (i.e., ICDAS 0, 0A, 3, and 5), as presented in Table 3. At six and 24 months follow-up, the incidence of caries and progression to cavitated caries (i.e., ICDAS 3 and 5) is extremely low. Further analysis showed that the difference in the incidence of caries between the two

Table 1. DEMOGRAPHIC VARIABLES RECORDED AT BASELINE AND SIX AND 24 MONTHS FOLLOW-UP*

Demographic variables	Baseline (N=47)		6 months (N=42)		24 months (N=33)		
	N	%	N	%	N	%	
Age (years)	9	15	31.9	13	30.9	12	36.3
	10	32	68.1	29	69.1	21	63.7
Mean±SD*	9.68±0.471		9.7±0.467		9.6±0.489		
Sex	Male	24	51.1	22	52.4	18	54.5
	Female	23	48.9	20	47.6	15	45.5
Ethnicity	Malay	45	95.7	40	95.2	33	100.0
	Indian	2	4.3	2	4.8	0	0

* SD=standard deviation; N=total number of school children in respective intervals. N=number of school children in respective demographic variables.

Table 2. RETENTION OF FISSURE SEALANTS APPLIED USING CONVENTIONAL ACID-ETCH AND SELF-ETCH TECHNIQUES ACCORDING TO SIMONSEN'S CRITERIA

Follow-up period	6 months‡				24 months			
	Conventional acid-etch		Self-etch		Conventional acid-etch		Self-etch	
	N	%	N	%	N	%	N	%
Completely retained	71	84.5	24	28.5	41	62.1	17	25.8
Partially retained	10	12.0	16	19.0	18	27.3	7	10.6
Completely lost	3	3.5	44	52.5	7	10.6	42	63.6
Total	84	100.0	84	100.0	66	100.0	66	100.0
P-value†	<0.001				<0.001			

* Simonsen's criteria of sealant retention (i.e., completely retained, partially retained, and completely lost)¹³.

† Chi-square test; level of significance is set at $P < 0.05$.

‡ N=number of teeth evaluated based on respective Simonsen's criteria at six and 24 months after sealant placement.

Table 3. INCIDENCE OF CARIES ON THE PITS AND FISSURES OF PERMANENT FIRST MOLARS BASED ON INTERNATIONAL CARIES DETECTION AND ASSESSMENT SYSTEM (ICDAS) SCORES*

Follow-up period ICDAS scores†	Baseline		6 months				24 months					
	Conventional acid-etch (N=94)		Self-etch (N=94)		Conventional acid-etch (N=84)		Self-etch (N=84)		Conventional acid-etch (N=66)		Self-etch (N=66)	
	N	%	N	%	N	%	N	%	N	%	N	%
ICDAS 0	59	70.2	60	71.4	59	70.2	56	66.7	45	68.2	43	65.2
ICDAS 0A	25	29.8	24	28.6	25	29.8	27	32.1	20	30.3	20	30.3
ICDAS 3	NA	NA	NA	NA	0	0	1	1.2	1	1.5	2	3.0
ICDAS 5	NA	NA	NA	NA	0	0	0	0	0	0	1	1.5
P-value‡	0.865		0.561				0.711					

* Incidence of caries between conventional acid-etch (control group) and self-etch (test group) evaluated based on ICDAS scores at baseline, six and 24 months follow-up; N=total number of teeth tested using conventional acid-etch and self-etch techniques at baseline, six and 24 months after sealant placement; NA=not applicable; N=number of teeth evaluated based on respective ICDAS scores at baseline, six and 24 months after sealant placement.

† ICDAS scores (i.e., ICDAS 0=sound tooth, ICDAS 0A=noncavitated caries lesion, ICDAS 3=cavitated lesion in enamel, and ICDAS 5=cavitated caries lesion in dentin).¹¹

‡ Chi-square test; level of significance=P<0.05.

techniques at baseline, six months, and 24 months follow-up was not statistically significant (P>0.05).

Discussion

Resin-based sealants have been considered effective in preventing caries on the occlusal surfaces of permanent dentition.¹⁴ In addition, pit and fissure sealants can reduce the progression of noncavitated occlusal caries.¹⁵⁻¹⁷ Clinical retention was used in assessing the ability of a sealant to preserve pits and fissures and in measuring durability. The full retention of sealants is a valid and quality indicator of sealant effectiveness.^{5,18,19}

Several in vitro studies investigated the sealing effectiveness of fissure sealant bonded with self-etch or total-etch modes using universal adhesive systems on the enamel surface.²⁰⁻²² However, no studies to date have compared universal self-etch mode adhesives and conventional acid-etch techniques regarding fissure sealant placement. The present study will contribute to evidence of the use of a self-etch mode (single step) in universal adhesive systems for enamel preparation before sealant placement. The Single Bond universal adhesive (Scotchbond™ Universal Etchant) was chosen for the current study because it contains a vitrobond copolymer, also known as polyalkenoic acid copolymer, which can bond chemically and naturally to hydroxyapatite alone with the standard universal adhesive system composition—such as functional monomer methacryloyloxydecyl dihydrogen phosphate.²³

This in vivo trial was designed to evaluate and compare the retention capabilities of self-etch adhesive and conventional acid-etching techniques in enamel preparation before resin-based sealant application in schoolchildren aged nine to 10 years and also to compare the incidence of caries six, 12, 18, and 24 months after the placement of pit and fissure in children with partial and total sealant dislodgement. However, in early March 2020, owing to the COVID-19 pandemic movement control order by the Malaysian government as a precautionary measure, follow-ups 12 and 18 months after

sealant application were not conducted. Since the early detection of retention failure was not achieved during the 12- and 18-month follow-ups, one participant showed active caries had progressed to ICDAS 5 at the 24-month follow-up.

In this trial, the mean age of the participants was 9.7 years, which was comparable to several fissure sealant trials conducted in the United Kingdom,²⁴ Kuwait,²⁵ and India.²⁶ The results of the study showed that the percentage of completely retained sealants (62.1 percent) in the molars treated with the conventional acid-etch technique was higher, and approximately 25.8 percent of completely retained sealants were observed in the enamel surfaces treated with the self-etch technique at 24 months follow-up. These results showed that full sealant retention was poor when the self-etch adhesive system was used, representing less than half of the total success rate in the conventional acid etching group. This finding was in agreement with the study of Karaman et al.,²⁷ that

reported that retention of nano-filled fissure sealants in the total-etch group (81.6 percent) were higher than those in the self-etch group (15.8 percent) at 24 months follow-up. The self-etch material used in a previous study was a sixth-generation one-step Futurabond® NR (Voco, Cuxhaven, Germany), while the total-etch used Solobond® M (Voco).²⁷

The etching or conditioning step is mainly used to remove the smear layer, selectively dissolve enamel rods, and produce macro- and microporosities. Capillary attraction prepares the porosities for penetration by hydrophobic material. Light polymerization induces micromechanical interlocking between etched enamel surfaces and tiny resin tags.²⁸ The main weakness of using the self-etch adhesive system for sealant retention may be attributed to the limited ability of self-etch adhesive materials to penetrate (creating tags) enamel surfaces. This limitation affects the bonding strength of fissure sealants. The penetration rates of adhesive materials increased when the enamel surface is etched with phosphoric acid.^{29,30}

The findings of the current trial were supported by the systematic review and meta-analysis of Botton et al.,¹⁰ who investigated the retention of fissure sealants in primary and permanent molars subjected to self-etch and conventional acid-etch or total-etch treatments. According to the systematic review, the retention of fissure sealants applied after conventional phosphoric acid-etching technique were higher than the self-etch technique.¹⁰

The outer layers of sound enamel surfaces are hypermineralized and contain more inorganic compounds than inner enamel surfaces.³¹ Therefore, the establishment of an appropriate etching pattern on uncut enamel surfaces remains the main issue in the use of the self-etching adhesives technique.³² The pH levels of adhesive systems are positively related to morphological changes in enamel surfaces. Moreover, a significant relationship was found between pH and mean bond strength.³³

The higher percentage of completely lost sealants treated with self-etch adhesive systems during six and 24 months

follow-up may be attributed to extreme pH levels, as both mild and ultra-mild self-etch adhesives cannot effectively etch uncut enamel surfaces and thus show insufficient resin penetration within the enamel.²⁷ Some self-etch adhesive systems are considered strong, with a pH of nearly one, such as Adper™ Prompt™ L-Pop (3M ESPE) and Prompt™ L-Pop (3M ESPE). Both systems are strong practically as conventional phosphoric acid etching systems.¹⁰ The difference in bond strength among various types of self-etch adhesives was determined by pH level. For instance, adhesive agents with low pH levels show low bonding strength, whereas those with high pH levels show high bonding strength when the time of the application is doubled.³⁴

Nevertheless, the findings of the current trial were not supported by the results of Feigal and Quelhas³⁵, who investigated a self-etching adhesive for sealant application at 24 months follow-up. Sealant application was successfully treated with the self-etch adhesive (Prompt™ L-Pop) and the conventional acid-etch system. A study also reported the efficiency of Prompt™ L-Pop in treating enamel surfaces before sealant application.³⁵ Maher et al.³⁶ evaluated the effectiveness of a self-etching adhesive (Prompt™ L-Pop) and conventional phosphoric acid etching in sealant retention in primary teeth. The results showed no statistically significant difference in sealant retention between groups treated with self-etching adhesives and the conventional acid-etching technique during six and 12 months of evaluation. The study concluded that replacing phosphoric acid etching with Prompt™ L-Pop does not compromise sealant retention.³⁶

A strong self-etch adhesive system dissolves smear layers nearly completely. However, dissolved calcium phosphate is not eliminated in the same manner as phosphoric acid because of the absence of a rinsing step in the self-etch system. This buried dissolved calcium phosphate reduces hydrolytic stability, potentially reducing interfacial integrity over time.²⁸ Scotchbond Universal™ (Universal Etchant) has been recognized as the first universal material to be commercialized worldwide. It has a pH level of 2.7, which is considered an ultra-mild acidic adhesive.³⁷

In vitro studies in Turkey²² and India³⁸ concluded that a self-etch mode associated with a universal adhesive system is comparable to conventional acid etching. Although *in vitro* studies described microleakages as useful for the evaluation of sealant quality and sealing ability, the findings of the studies may not represent results under clinical conditions. Furthermore, the inconsistent findings of studies regarding fissure sealants treated with self-etch adhesive systems can be due to the use of different generations and brands of adhesives.

Although the self-etch adhesive group showed a lower retention rate, no statistically significant difference was found between the test (self-etch) and control (conventional acid-etch) groups concerning the incidence of caries at six and 24 months follow-up. The findings of the present trial were in accordance with the study of Mohammed et al.²⁶, who compared the effectiveness of traditional acid etching and a self-etching agent in sealant retention.²⁶ The study reported no significant difference in the incidence of caries between the test and control groups at a six-month follow-up. Burbridge et al.²⁴ reported a similar finding, indicating no significant difference in the incidence of caries between the occlusal surfaces in the test and control groups after 12 months. By contrast, studies in the United Kingdom,²⁴ Turkey,³⁹ and Iran⁴⁰ indicated no incidence of caries at 24 months follow-up.

The caries incidence results in the current study indicate that the development of occlusal caries is not related to the technique used to prepare the tooth surface before the fissure sealant application, but sealant retention is the main factor. The lost fissure sealants were repaired by either using the control technique for noncavitated teeth or composite restoration for the cavitated teeth and not allowing caries to progress. Therefore, long-term follow-up was not possible. It is acknowledged that the caries incidence is extremely low in the present study, which contributed to caries data not being sufficiently powered to assess differences between the control and intervention groups. Future studies may consider increasing the sample size to overcome this limitation.

In addition, the present study has some limitations, including a reduction in the number of follow-ups (i.e., 12 and 18 months follow-up) due to the implementation of a lockdown amid the COVID-19 pandemic. Factors such as the transfer of children from school and absence during follow-up are also considered limitations. However, except for data collected during the 12- and 18-month follow-ups, the overall findings of the trial were unaffected, potentially providing valuable information regarding the retention capabilities of fissure sealants and the incidence of caries.

Conclusions

Based on this study's results, the following conclusions can be made:

1. The self-etch mode in the universal adhesive system is not effective in bonding resin-based fissure sealant to the enamel surface.
2. Resin-based fissure sealant placement using the conventional phosphoric acid-etching technique presents the greatest retention rate at six and 24 months follow-up, which can be useful to clinicians to avoid repeating the same procedure within a short time.
3. The sealant loss in the self-etch group occurred early, with more than half of the sealants completely lost by the six-month follow-up.
4. Both techniques showed comparable results regarding the incidence of caries at six and 24 months follow-up.

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